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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

NATIONAL KIDNEY PATIENTS ASSOCIATION, *et al.*,
Petitioners,

v.

LOUIS W. SULLIVAN, M.D.,
SECRETARY OF THE UNITED STATES DEPARTMENT
OF HEALTH AND HUMAN SERVICES, *et al.*,
Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMICUS CURIAE BRIEF OF

American Medical Association
American Academy of Dermatology
American Academy of Orthopaedic Surgeons
American College of Radiology
American College of Radiation Oncology
American Group Practice Association
American Psychiatric Association
American Psychological Association
American Society of Cataract and Refractive Surgery
American Society of Outpatient Surgeons
American Society of Ophthalmic Administrators
Association of Freestanding Radiation Oncology Centers
Federated Ambulatory Surgery Association
Group Health Association of America
Outpatient Ophthalmic Surgery Society
National Association of Diagnostic Services

IN SUPPORT OF THE PETITION

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National Association of Diagnostic Services

IN SUPPORT OF THE PETITION

Pursuant to Rule 37.2 of the Rules of this Court, the associations named above submit this brief as *amici curiae* in support of the Petition for a Writ of Certiorari to the Court of Appeals for the District of Columbia Circuit filed by Petitioners, National Kidney Patients Association, *et al.*, on September 29, 1992. Consent to the filing of this brief has been granted by the parties.

INTEREST OF THE AMICI CURIAE

Medicare is the primary source of health insurance for America's elderly and disabled citizens. The program covers more than 35 million beneficiaries, at an annual cost to the federal government of approximately $145 billion.[1] The *amici curiae* are professional and trade associations whose members provide items or services to Medicare beneficiaries and who are entitled to payment from Medicare for such items and services.[2]

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[1] Part A of the program provides coverage primarily for inpatient hospital services. Part B authorizes payment for various medical services and supplies.

[2] The American Medical Association is the largest organization representing physicians in the United States, having approximately 280,000 members. The American Academy of Dermatology is a private, nonprofit medical specialty society with over 8,900 members and is the largest medical organization of dermatologists in the world. The American Academy of Orthopaedic Surgeons is the primary educational and professional organization of orthopaedic surgeons in the United States; its membership includes nearly 18,500 orthopaedic surgeons, including approximately 95% of the board-certified orthopaedic surgeons in the United States. The American College of Radiology is the principal organization of radiologists and medical radiation physicists in the United States, with more than 28,000 members. The American College of Radiation Oncology is a professional association of approximately 1,000 physicians and other professionals specializing in the use of radiation to treat cancer. The American Group Practice Association represents the vast majority of the nation's large, multispecialty medical group practices. The American Psychiatric Association is the nation's largest professional association of psychiatrists, with more than 35,000 members.

As such, *amici* have a strong interest in the fair, efficient administration of Medicare and in the ability of aggrieved providers of health care services and beneficiaries to obtain timely, effective judicial review of agency actions affecting the administration of the program.

Amici believe that these interests will be severely damaged if the decision of the D.C. Circuit at issue here is left intact. The potential consequences of the D.C. Circuit's decision are of such overriding importance to both Medicare beneficiaries and providers that the decision requires immediate review by this Court.

The American Psychological Association is the principal professional association of psychologists in the United States; it has more than 100,000 members, including the vast majority of doctoral-level psychologists. The American Society of Cataract and Refractive Surgery is a scientific and educational association of approximately 5,000 ophthalmologists who are specially interested in cataract/intraocular lens implantation surgery and corneal refractive surgery. The American Society of Outpatient Surgeons is a professional association of approximately 400 physicians, from a wide variety of specialty areas, who specialize in the performance of outpatient surgical procedures. The American Society of Ophthalmic Administrators is a professional organization of approximately 1,800 individuals dedicated to the improvement of medical practice management. The Association of Freestanding Radiation Oncology Centers is a trade association representing over 200 non-hospital providers of radiation therapy services. The Federated Ambulatory Surgery Association is a national membership organization of over 400 ambulatory surgery centers, representing approximately 2,000 physicians, nurses, and health administrators at these facilities. The Group Health Association of America is a national trade association representing 335 managed care companies, often referred to as health maintenance organizations ("HMOs"), which provide health care services to 28 million Americans, including 1.8 million Medicare beneficiaries. The Outpatient Ophthalmic Surgery Society is a professional society of approximately 800 ophthalmologists having a particular interest in the use of the outpatient setting. The National Association of Diagnostic Services is a nonprofit association of physiological laboratories and equipment suppliers that provide diagnostic imaging services, including ultrasound, mammography, and nuclear medicine services.

SUMMARY OF ARGUMENT

The D.C. Circuit's decision means that the legality of Medicare regulations and national policies may be adjudicated in that Circuit only after exhaustion of a lengthy, burdensome, and inevitably futile administrative review process. Not only will this decision result in a substantial waste of private, administrative, and judicial resources, it will, as a practical matter, entirely preclude *any* review in many cases and will make it impossible for trade and professional associations such as *amici* to obtain timely, consolidated review on behalf of all of their affected members. Moreover, even if other Circuits could be persuaded to adopt a different view, the resulting intercircuit conflict will make eventual review by this Court virtually inevitable, so that beneficiaries and providers who seek relief in other Circuits risk incurring substantial retroactive damages. The D.C. Circuit's decision will thus leave the Medicare program almost entirely insulated from effective judicial oversight.

ARGUMENT

In *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986) (hereafter "*Michigan Academy*"), this Court held that general federal question (28 U.S.C. §1331) jurisdiction is available for disputes involving the "method" by which amounts paid under the Medicare program are determined. Specifically, this Court made it clear that 42 U.S.C. §1395ff(b)(1)(C), which by its terms governs disputes concerning the "amount" of Medicare benefits, does not apply to disputes involving "the method by which such amounts are to be determined." *Michigan Academy*, 476 U.S. at 675. Under the principles set forth in *Michigan Academy*, while a dispute involving the "amount" of payment can only be brought in federal court after the administrative review process provided by 42 U.S.C. §1395ff(b)(1)(C) has been exhausted, "method" challenges may be brought directly to federal court under Section 1331.

Although most Medicare regulations have been implemented without challenge, the federal courts have relied on *Michigan Academy* on numerous occasions to correct agency actions that were found to be inconsistent with the Medicare statute or with the Administrative Procedure Act, 5 U.S.C. §551 *et seq.* *See, e.g., Linoz v. Heckler*, 800 F.2d 871 (9th Cir. 1986) (invalidating Medicare Carrier Manual provision that effectively denied reimbursement for ambulance services); *Medics, Inc. v. Sullivan*, 766 F. Supp. 47 (D.P.R. 1991), *aff'd sub nom. La Casa Del Convaleciente v. Sullivan*, 965 F.2d 1175 (1st Cir. 1992) (successful procedural challenge to agency's policy regarding payment for certain items of durable medical equipment); *American Lithotripsy Society v. Sullivan*, 785 F. Supp. 1034 (D.D.C. 1992) (enjoining implementation of the initial payment rate established by the agency for lithotripsy services); *American Society of Cataract & Refractive Surgery v. Sullivan*, 772 F. Supp. 666 (D.D.C. 1991), *appeal docketed* (enjoining agency's withdrawal of Medicare coverage for intraocular lenses that have not received full Food and Drug Administration approval). It is therefore crucial that beneficiaries and providers retain access to a forum where they can obtain timely national determinations of the legality of Medicare regulations and national policies.[3]

The D.C. Circuit's decision in *National Kidney Patients Association v. Sullivan*, 958 F.2d 1127 (D.C. Cir. 1992), *petition for cert. filed* (Sept. 29, 1992) (hereafter "*NKPA*"), effectively nullifies *Michigan Academy* by ruling that the federal courts no longer have jurisdiction to hear such "method" challenges under Section 1331. The D.C. Circuit rationalizes its departure from

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[3] The *amici curiae* associations have themselves brought several such challenges. *See, e.g., American Society of Cataract & Refractive Surgery v. Sullivan, supra*; *Outpatient Ophthalmic Surgery Society, Inc. v. Sullivan, jurisdictional ruling reported at* [1991 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 38,981 (D.D.C. December 14, 1990), *decision on merits pending.*

this Court's clear holding by claiming that Congress mandated this result when it enacted Section 9313(b) of the Omnibus Budget Reconciliation Act of 1986 (hereafter "the 1986 amendments"). According to the D.C. Circuit, the 1986 amendments, which *expanded* judicial review under 42 U.S.C. §405(g) of *individual* claims regarding the amount of benefits payable under Part B of the Medicare program, implicitly eliminated Section 1331 jurisdiction over broader challenges to the methods used to calculate benefit amounts, including challenges to the legality of Medicare regulations. As a result, the Circuit held, 42 U.S.C. § 405(g)—with its requirement for exhaustion of all administrative remedies—now represents the sole jurisdictional basis for these "method" challenges. The D.C. Circuit reached this conclusion even though such "method" challenges generally cannot be resolved through the administrative review process.

This Court's early review of the D.C. Circuit's decision is essential. The decision deprives Medicare beneficiaries and providers of timely access to the D.C. Circuit for the resolution of important disputes concerning the legality of Medicare regulations and national policies. This lack of access to the D.C. Circuit cannot be remedied by seeking relief in other Circuits, because the D.C. Circuit is the *only* Circuit in a position to issue definitive national determinations with respect to the legality of Medicare regulations and national policies. And even in cases where another Circuit might potentially be able to provide relief, the existence of the *NKPA* decision leaves Medicare beneficiaries and providers in an untenable state of uncertainty with respect to the appropriate route for challenging allegedly illegal Medicare regulations or national policies — uncertainty which will, as a practical matter, leave the Medicare program essentially free of judicial oversight.

I. The D.C. Circuit's Decision Places Substantial, Inappropriate, And Unnecessary Obstacles In The Path Of Parties Seeking To Challenge The Validity Of Medicare Regulations And National Policies In The D.C. Circuit.

By requiring exhaustion of the administrative review process even for "method" challenges, the D.C. Circuit's decision in *NKPA* places substantial — and utterly unnecessary — obstacles in the way of beneficiaries and providers seeking federal court review of illegal agency action. Indeed, as a practical matter, the D.C. Circuit's insistence that beneficiaries and providers exhaust the administrative review process before instituting suit will entirely preclude review in the D.C. Circuit in many cases.[4]

The burden imposed on individual claimants by the administrative review process mandated by the D.C. Circuit is substantial. Specifically, a beneficiary or supplier seeking to challenge an allegedly illegal Medicare regulation first must request that its carrier[5] "review" the amount paid by the carrier pursuant to the challenged regulation. *See* 42 C.F.R. §405.807. This step must be completed even though the carriers are bound

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[4] The Second Circuit has already decided to follow the D.C. Circuit's lead with respect to the jurisdictional issue involved here. In *Abbey v. Sullivan*, ___ F.2d ___, 1992 WL 238053 (2d Cir. September 28, 1992), the Second Circuit adopted the D.C. Circuit's jurisdictional analysis, essentially without further elaboration. The Second Circuit reached this conclusion even though the dispute in *Abbey* could have been resolved through the administrative appeals process. In other words, the case arguably did not involve a "method" dispute within the meaning of *Michigan Academy*, so that the Second Circuit did not need to address the question raised in *NKPA*. Nevertheless, in light of *Abbey*, the barriers to judicial review that *NKPA* created for the D.C. Circuit now appear to apply in the Second Circuit as well.

[5] Carriers are private insurance companies engaged by the Secretary of Health and Human Services to process Medicare Part B claims.

to pay claims in accordance with Medicare regulations and other policies established by the agency and there is consequently nothing for the carrier to "review."

After the carrier completes its "review," the beneficiary or provider must request a hearing before a hearing officer — who likewise has no authority to deviate from payment methodologies set forth in Medicare regulations. *See* 42 C.F.R. §§405.820, 405.860. Since carriers conduct in excess of 30,000 hearings per year, this stage of the proceedings can be quite lengthy. In the experience of the *amici curiae* associations, from the time an appeal is initiated until the time the hearing officer renders his decision is generally several months, and can be a year or more.

After the hearing officer renders his decision, the beneficiary or provider must then appeal that decision to an administrative law judge ("ALJ") within the Social Security Administration. The ALJ, however, is also powerless to overturn Medicare regulations. *See* 53 Fed. Reg. 20023-24 (June 1, 1988) (providing that Medicare Part B appeals will be heard by Social Security ALJs and governed by 20 C.F.R. Part 404, Subpart J). According to a report from the General Accounting Office, the average time between the date an on-the-record hearing is requested and the date the decision is finally rendered by an ALJ is 154 days. GAO Rep. No. HRD-90-18 (November 28, 1989).

Finally, the ALJ's decision must be presented to the Appeals Council of the Department of Health and Human Services, even though it too is bound by the Secretary's regulations and other determinations. *See* 20 C.F.R. §404.967. Review by the Appeals Council can likewise involve substantial delays. Still, under the D.C. Circuit's decision, federal court action could not be initiated until the Appeals Council has rendered its decision.[6]

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[6] After presenting their claims, aggrieved parties arguably could institute suit in federal court under 42 U.S.C. §§ 405(g), 1395ff(b)(1)(C) and request

This lengthy, repetitive process would have to be followed by *each* individual beneficiary or provider interested in obtaining relief from an allegedly illegal Medicare regulation or policy. Indeed, while claims could be grouped together, each beneficiary or provider would likely be required to pursue several *separate* appeals, since under the regulations the right to administrative review of a particular claim is lost unless an appeal is initiated within six months of the carrier's initial determination on that claim. 42 C.F.R. §405.807(c). Thus, to fully protect their rights, providers who regularly furnish services affected by a challenged regulation or policy would have to initiate a new appeal at least once every six months until the matter is finally resolved. Similarly, requests for judicial review of an Appeals Council decision must be filed within 60 days of that decision, 20 C.F.R. §404.981, so that a provider who wishes to fully preserve his rights may ultimately need to initiate multiple federal court actions on the identical issue. In any event, even if an individual beneficiary is able to surmount these hurdles, the barriers posed by the administrative review process make it virtually impossible for any of the *amici* to do what could have been done prior to the D.C. Circuit's decision in *NKPA* — file a single suit challenging the regulation or policy at issue on behalf of all of their members.[7]

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waiver of exhaustion of the administrative process on the ground that exhaustion would be futile. However, this Court has sanctioned waiver of the exhaustion requirement only under limited circumstances. Specifically, this Court has held that the "statutorily specified jurisdictional prerequisite" in 42 U.S.C. § 405(g) is "something more than simply a codification of the judicially developed doctrine of exhaustion, and may not be dispensed with merely by a judicial conclusion of futility." *Weinberger v. Salfi*, 422 U.S. 749, 766 (1975). Moreover, the federal courts have never sanctioned waiver in a case involving providers (as opposed to beneficiaries).

[7] It may be possible for an association to file a class action challenging the legality of a particular regulation; however, unless the court waives the requirement that administrative remedies be exhausted, such a suit likely could not be brought until several association members had completed the

In short, requiring beneficiaries and providers to proceed individually through this lengthy review process would deluge the carriers, the ALJs, and the Appeals Council with complaints they have no authority to redress, at substantial cost to both private litigants and the Medicare program. Indeed, just handling such appeals will inevitably cause delays in the review of individual claims for benefits, the only type of case for which the administrative review process was designed. The courts, too, will eventually be faced with a profusion of virtually identical cases instead of the efficient, consolidated approach permitted under *Michigan Academy*. Clearly, the route mapped out by the D.C. Circuit does not provide a practical means of obtaining judicial oversight of the Medicare program.

The issue is not merely one of time and expense. There are numerous situations where the Part B administrative review process will effectively preclude *any* judicial review of Medicare regulations and policies. For example, consider the factual circumstances underlying the case of *American Lithotripsy Society*, *supra*, in which an association challenged the initial payment rate established for lithotripsy services provided in ambulatory surgical centers ("ASCs").[8] The plaintiffs in that case argued that the Health Care Financing Administration ("HCFA"), which administers the Medicare program, employed a ratesetting methodology for which there was no support in the administrative record, and contended that the rate adopted by HCFA was inconsistent with the information supplied by the public commenters. The District Court agreed,

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entire administrative review process. Even then, nationwide relief would probably be unavailable, as membership in the class would likely be limited to those who had completed the administrative review process and who individually met the amount in controversy threshold for filing in federal court.

[8] Lithotripsy involves the use of sound waves, administered from outside the body, to pulverize kidney stones, allowing treatment of this condition without invasive surgery.

issuing an order that enjoined HCFA from implementing the challenged rates and that directed HCFA to pursue further administrative proceedings.

Such direct and timely review, however, would have been impossible under the principles set forth in *NKPA*. Rather, to secure review under *NKPA*, an individual ASC would have had to purchase and install a lithotripsy machine at a cost of $1 million or more; provide lithotripsy services to Medicare patients; file claims for these services with the carrier; receive payment for those claims at the rate established by HCFA; and exhaust all of the administrative appeals described above. Only then could the facility have brought its challenge to federal court. Clearly, it is unrealistic to expect effective judicial review of the agency's action to emerge from such a set of requirements. In fact, it is likely that an ASC faced with the rate for lithotripsy services initially established by HCFA would simply decline to provide those services to Medicare beneficiaries, rather than invest the time and expense that would be required to challenge the rate through the process mandated by *NKPA*.

Not only is the Part B administrative review process mandated by *NKPA* unwieldy and extremely burdensome, it is completely unavailable to some types of providers. For example, many health maintenance organizations participating in the Medicare program do not file claims for benefits on an ongoing basis with Medicare carriers; rather, they are paid directly by HCFA on the basis of a cost report filed annually. It appears that such entities could not meet the jurisdictional prerequisites for filing suit under 42 U.S.C. §§405(g), 1395ff(b), and there is no apparent alternative route to federal court available to them.

This Court addressed an analogous set of facts just last year in *McNary v. Haitian Refugee Center, Inc.*, 111 S. Ct. 888 (1991). The plaintiffs in *McNary* were a class of illegal aliens seeking amnesty under recent amendments to the federal im-

migration statute. They sought to contest the interpretation given to the amendments by the Immigration and Naturalization Service ("INS"). The INS took the position that the plaintiffs' challenge could only be heard following administrative review of individual claims for amnesty. This Court rejected the INS's arguments, holding that "if not allowed to pursue their claims in the District Court, respondents would not as a practical matter be able to obtain meaningful judicial review of their application denials or of their objections to INS procedures." *Id.* at 898. If the *NKPA* decision is allowed to stand, it is clear that, as in *McNary*, Medicare beneficiaries and providers "[will] not as a practical matter be able to obtain meaningful judicial review" of illegal agency action.

II. It Is Crucial For Beneficiaries And Providers To Have Timely Access To The D.C. Circuit For Disputes Involving The Legality Of Medicare Policies Because The D.C. Circuit Is The Only Circuit In A Position To Issue Determinative National Rulings On These Issues.

The D.C. Circuit's decision in *NKPA* is especially important because that Circuit has historically played a unique role in determining the legality of Medicare regulations and national policies. Cases brought under *Michigan Academy* as well as certain other types of Medicare cases can generally be brought either in the District of Columbia or in the district where the plaintiff resides. *See* 28 U.S.C. §1391; 42 U.S.C. §1395oo. As a result, the D.C. Circuit has had to intervene frequently to invalidate Medicare regulations. *See, e.g., Georgetown Univ. Hosp. v. Bowen*, 862 F.2d 323 (D.C. Cir. 1988) (invalidating Medicare regulation governing calculation of "hospital-specific rate" for inpatient hospital care); *PIA-Asheville, Inc. v. Bowen*, 850 F.2d 739 (D.C. Cir. 1988) (invalidating Medicare regulation governing reevaluation of assets following change of ownership); *St. Mary of Nazareth Hosp. Center v. Heckler*, 760 F.2d

1311 (D.C. Cir. 1985) (invalidating nationwide HCFA policy regarding method of apportioning costs between Medicare and non-Medicare patients); *Walter O. Boswell Memorial Hosp. v. Heckler*, 749 F.2d 788 (D.C. Cir. 1984), *on remand*, 628 F. Supp. 1121 (D.D.C. 1985) (invalidating regulation governing allocation of malpractice-related expenses).

Significantly, the D.C. Circuit is the only Circuit that is in a position to issue conclusive national rulings regarding the legality of a Medicare regulation or national policy. When a challenge to a Medicare regulation is brought in another Circuit and the regulation is determined to be invalid by that Circuit, HCFA has frequently "nonacquiesced" in the unfavorable decision, continuing to litigate the same issue in other Circuits. This process generally continues until some plaintiff or set of plaintiffs obtains a favorable decision from the D.C. Circuit. Only then is the matter finally resolved, since other potential litigants can then seek similar relief from the D.C. Circuit. Thus, definitive, nationally applicable rulings concerning the legality of Medicare regulations historically have been available only in the D.C. Circuit, a forum which *NKPA* makes virtually inaccessible.[9]

Probably the best example of the impact of such "nonacquiescence" in the context of the Medicare program involves the litigation over the so-called "1979 malpractice rule," in which numerous providers challenged a regulation reducing payments to hospitals for the cost of malpractice insurance and related expenses. HCFA continued to litigate this issue until it became clear that the agency would lose in the D.C. Circuit, at which point HCFA offered a settlement. *See Abington Memorial*

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[9] Not only does *NKPA* require exhaustion of administrative remedies before suit may be filed in the D.C. Circuit, under 42 U.S.C. § 405(g), the only jurisdictional basis for Part B cases that will remain if *NKPA* is upheld, suit must be filed in the district where the plaintiff resides or does business, entirely precluding access to the D.C. Circuit in many cases.

Hosp. v. Heckler, 750 F.2d 242 (3d Cir. 1984), *cert. denied*, 474 U.S. 863 (1985); *Bedford County Memorial Hosp. v. HHS*, 769 F.2d 1017 (4th Cir.), *on remand*, 660 F. Supp. 23 (E.D. Va. 1985); *DeSoto Gen. Hosp. v. Heckler*, 766 F.2d 182 (5th Cir. 1985); *St. James Hosp. v. Heckler*, 760 F.2d 1460 (7th Cir.), *cert. denied*, 474 U.S. 902 (1985); *Menorah Medical Center v. Heckler*, 768 F.2d 292 (8th Cir. 1985); *Humana of Aurora, Inc. v. Heckler*, 753 F.2d 1579 (10th Cir.), *cert. denied*, 474 U.S. 863 (1985); *Lloyd Noland Hosp. & Clinic v. Heckler*, 762 F.2d 1561 (11th Cir. 1985); *Walter O. Boswell Memorial Hosp., supra.*

Another example involves the series of cases known as the "labor/delivery room cases," in which hospitals challenged the way in which HCFA treated costs associated with labor and delivery rooms. Again, HCFA continued to litigate the issue until a definitive ruling adverse to HCFA was obtained in the D.C. Circuit; only at that point did HCFA abandon the fight and agree to apply the D.C. ruling to all pending cases. *See* HCFA Ruling 87-3, 52 Fed. Reg. 13873 (April 27, 1987).

Thus, by depriving Medicare beneficiaries and providers of health care services of timely access to the D.C. Circuit to challenge the validity of Medicare regulations and national policies, the D.C. Circuit has paved the way to duplicative legal challenges to the validity of Medicare regulations and national policies and has thereby struck a substantial blow against administrative and judicial efficiency and economy. Since challenges to the validity of Medicare regulations and national policies often raise complex issues and require judicial review of lengthy administrative records,[10] the excess litigation that will result from this decision will impose a substantial additional burden on the already busy dockets of the federal courts.

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[10] For example, the administrative record in *Outpatient Ophthalmic Surgery Society v. Sullivan, supra*, consists of more than 3,000 pages.

III. The D.C. Circuit's Decision Leaves Beneficiaries And Providers In An Untenable State Of Uncertainty That Can Only Be Resolved By This Court.

As Petitioners demonstrate, the D.C. Circuit's decision conflicts with the decisions of other Circuits.[11] *See* Pet. at 19. Nevertheless, beneficiaries and providers seeking to challenge a Medicare regulation or policy cannot reliably avoid the impact of the D.C. Circuit's decision by instituting suit in another Circuit.

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[11] The D.C. Circuit itself acknowledges this conflict. *See* Pet. App. at 15a. Moreover, the reasoning used by the D.C. Circuit (and, now, the Second Circuit) is implicitly inconsistent with that of the First and Seventh Circuits. The D.C. and Second Circuits have both held that, as the result of enactment of the 1986 amendments, the term "amount," as used in 42 U.S.C. § 1395ff(b)(1)(C), includes the method for determining the amount of benefits. These Circuits have therefore held that individuals seeking to mount "method" challenges must exhaust the administrative appeals process prescribed in this section before seeking review in federal court. Although the rulings of the D.C. Circuit and the Second Circuit came in cases arising under Part B of Medicare, the relevant statute now makes no distinction between Part A and Part B; accordingly, their rulings would appear to apply to Part A as well. On the other hand, the First and Seventh Circuits have rendered decisions indicating that the amount/method distinction made by *Michigan Academy* continues to be good law for Part A disputes. *See McCuin v. Secretary of Health & Human Services*, 817 F.2d 161, 165 (1st Cir. 1987); *Bodimetric Health Services, Inc. v. Aetna Life & Casualty*, 903 F.2d 480, 484-87 (7th Cir.), *cert. denied*, 111 S. Ct. 579 (1990). These decisions implicitly suggest that the term "amount" as used in Section 1395ff(b)(1)(C) does *not* include "method" challenges under either Part A or Part B. At least two District Court decisions rendered since the D.C. Circuit's decision in *NKPA* have recognized this intercircuit conflict. In *Pulmocare Pharmacy, Inc. v. Sullivan*, Medicare and Medicaid Guide (CCH) ¶ 40,387 at 31,600 (D. Or. June 12, 1992), the U.S. District Court for the District of Oregon rejected *NKPA*'s jurisdictional analysis; in *Cardiac Monitoring Services, Inc. v. Blue Cross & Blue Shield of Arkansas*, ___ F. Supp. ___, 1992 WL 314073 (E.D. Ark. Aug. 6, 1992), the District Court for the Eastern District of Arkansas accepted it.

More specifically, consider the outlook for a beneficiary or provider (or an association acting on behalf of its members) that, in reliance on *Michigan Academy*, brings suit challenging a Medicare regulation outside the D.C. Circuit under Section 1331. Assume that this plaintiff wins a favorable ruling in District Court on both the jurisdictional issue and the merits, and that the decision is upheld by the appropriate Court of Appeals. Supreme Court review of the appellate decision then becomes almost certain, given the unavoidable intercircuit conflict that will have emerged concerning the issue in *NKPA*.

Should this Court, in reviewing such a decision, then decide that the D.C. Circuit's position on the jurisdictional issue is correct, whatever relief may have been awarded at the Circuit level will be vacated. Moreover, and potentially more seriously, the beneficiary or provider that brought the original action could find itself liable for substantial retroactive payments. For example, as a result of the D.C. Circuit's decision in *NKPA*, petitioner Home Intensive Care now allegedly faces *retroactive* recoupment of $15 million that it received pursuant to the injunction awarded by the District Court. *See* Pet. App. at 2a. And while *NKPA* involves only one supplier located primarily in one carrier jurisdiction and involves only one relatively minor component of the Medicare program, other "method" challenges may involve substantially greater exposure for retroactive recoupments.

Until this Court definitively resolves the jurisdictional issue presented in NKPA, this risk of retroactive recoupment will be present any time a beneficiary, provider, or association relies on the principles of *Michigan Academy* to challenge a Medicare regulation or national policy, regardless of the Circuit in which such a challenge is brought. Consequently, the D.C. Circuit's position with regard to the continued vitality of *Michigan Academy* will, as a practical matter, have a *national* impact, dramatically increasing for parties throughout the

country the risks of challenging even the most serious violations of the Medicare statute or the Administrative Procedure Act. It is plainly unfair to expect Medicare beneficiaries and providers (and their organizational representatives) to absorb these risks indefinitely. It is therefore essential that this Court act promptly to set aside the D.C. Circuit's decision and ensure the availability of timely judicial review of regulations and other policies affecting the administration of the Medicare program.

CONCLUSION

For the reasons set forth above, the *amici curiae* respectfully request this Court to grant the Petition for a Writ of Certiorari.

Respectfully submitted,

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